July 16, 1999

FDA Public Health Notification:
Important Y2K Planning Information

To: Hospital/Healthcare Facility Administrators
Risk Managers
Biomedical/Clinical Engineers

I am writing to remind you about the Year 2000 (Y2K) remediation and contingency planning needed for date-related computer-controlled medical devices, to give you information to assist you in your planning, and to encourage you to promptly report certain Y2K problems to our MedWatch database. The Food and Drug Administration (FDA) believes that only a few types of devices have a potential to present a significant risk to patients as a result of a Y2K failure. I encourage every healthcare facility to assess its biomedical equipment and automated systems and to develop a contingency plan as soon as possible.

Y2K Contingency Plan

Your facility must have a Y2K contingency plan to:

- Address unforeseen events that might occur from the date-related problems with computer-controlled medical devices and other systems.
- Assess the impact of non-compliant Y2K devices on your ability to provide care.
- Identify necessary actions to take if a medical device experiences an unexpected failure.

Information to Assist in Your Planning

The following information sources can assist in your planning for Y2K problems with computer-controlled medical devices:

- List of computer-controlled medical devices considered potentially high risk for causing serious adverse events. You may want to focus your attention on this information as you develop or update your contingency plan. You will find this list on the Federal Y2K Biomedical Equipment Clearinghouse site:
  http://www.fda.gov/cdrh/yr2000/year2000.html
  Select Information for Healthcare Facilities.
- Department of Veterans Affairs' (VA) Y2K Contingency Planning Guide:
  http://www.va.gov/year2000
- VA's Year 2000 Medical Device Assessment Guide:
  http://www.va.gov/year2000/mdguide.pdf

Issues to Consider in your Contingency Plans

- The adverse impact of stockpiling medical devices such as the potential for induced shortages and increased costs (also on drugs and biologics). Watch for results of a White House-sponsored meeting on this subject.
- Any computer systems that contain patient records and other significant data.

Federal Y2K Biomedical Equipment Clearinghouse

At FDA's request, manufacturers provided detailed information regarding the Y2K status of biomedical equipment for inclusion in the database provided at this web site. This database was developed for the convenience of healthcare facilities and device users. The site contains two kinds of information for your use.

- Y2K Non-Compliant Products – Information on non-compliant products, as well as more detailed descriptions of how products will operate as a result of their uncorrected date problem*
- Y2K Compliant Products – Information on specific product models that are Y2K compliant*

MedWatch Reporting Database

I would like to remind you about reporting adverse events to FDA's MedWatch Reporting Database.

- **Mandatory Reports**

  What to Report? As with any device-related death or serious injury in your facility, you are required to report deaths to FDA and the manufacturer and injuries to the manufacturer only. Please report these problems through procedures established by your facility; identify the report as a Y2K problem.

- **Voluntary Reports**

  What to Report? Any date-related problem that did not cause death or injury but caused unexpected performance, for example, a malfunction that could cause death or serious injury ***if the problem recurred***. We encourage you to report any contradiction between your device findings and those findings claimed by the manufacturer. Please identify your report as a Y2K problem.

* *FDA cannot guarantee the accuracy or completeness of the information provided by manufacturers.*

- **How Do I Report?**
  - By telephone to 1-800-FDA-1088
  - By FAX, use Form 3500 to 1-800-FDA-0178
  - By Mail, use Form 3500, to
    MedWatch
    Food and Drug Administration, HF-2
    5600 Fishers Lane
    Rockville, MD 20857-9787
  - Electronically at: http://www.fda.gov/medwatch/index.html

The Y2K or other date-related computer problems that could possibly occur on January 1, 2000 could affect some medical devices ***at other times*** during 1999 if programs that anticipate dates beyond January 1, 2000 are used.

I hope this information will help you and your organization. I know you share our concern and our commitment to assure the safe delivery of patient care as we approach the year 2000.

Sincerely yours,

David W. Feigal, Jr., M.D., M.P.H.
Director,
Center for Devices and Radiological Health